510(K) SUMMARY

NOV 2 9 2000

PRODUCT, CLASSIFICATION NAME

Delta 32 with optional add-on TACT®
(Mammographic biopsy and spot imaging system)

System, x-ray, mammographic/ IZH

Regulation number: 892.1710

MANUFACTURER:

Instrumentarium Corp. Imaging Division
P.O.Box 20 (Street Address: Nahkelantie 160)
FIN-04301 Tuusula, Finland

Phone: +358-10-394 6500
Fax: +358-10-394 6501

Contact person: Tommi Jokiniemi

UNITED STATES SALES REPRESENTATIVE (U. S. DESIGNATED AGENT):

Instrumentarium Imaging Inc.
300 West Edgerton Avenue
Milwaukee, Wisconsin 53207

Phone: 414-747-1030
Fax: 414-481-8665

INTENDED USE:

Delta 32 and Delta 32 TACT® are intended to be used for digital stereotactic breast biopsy and spot mammographic imaging with the base mammographic system Diamond. The TACT® add-on provides means for digital 3D spot imaging using 2D projection images acquired with the system.

DESCRIPTION:

Delta 32 (TACT®) is a mammographic digital stereotactic biopsy and spot imaging system. The base system is the Diamond mammographic system (#K955411), on which the Delta 32 (TACT®) is installed.

The images are acquired by a CCD camera and stored and viewed by a PC workstation. The needle guiding system is a Cytoguide biopsy unit for which the Delta 32 computes the necessary needle coordinates. The workstation also performs the optional TACT® 3D reconstruction and viewing of reconstructed volume in either slices or in pseudohologram.

SUBSTANTIAL EQUIVALENCE:

We consider this product is similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

Delta 16	#K955411
Delta 16 TACT®	#K001171

The comparison of characteristics of the fully operational systems supports substantial equivalence. The Delta 32 with optional TACT® integrates the features of the predicate devices to the new platform Diamond.

The intended uses are essentially equivalent: The intended use of Delta 32 (TACT®) includes biopsy and spot imaging like the intended uses of the predicate devices.

Instrumentarium Corp. Imaging Division

Tommi Jokiniemi
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2000

Tommi Jokiniemi
Regulatory Affairs Engineer
Instrumentarium Imaging, Inc.
300 West Edgerton Avenue
Milwaukee, Wisconsin 53207

Re: K002472
Delta 32 with optional TACT® add-on
(Mammographic Biopsy and Spot
Imaging System)
Dated: November 2, 2000
Received: November 13, 2000
Regulatory Class: II
21 CFR 892.1710/Procode: 90 IZH

Dear Mr. Jokiniemi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): #K002472

Device Name: Delta 32 with optional add-on TACT®

Indications for Use: Delta 32 and Delta 32 TACT® are intended to be used for digital stereotactic breast biopsy and lesion localization with the base mammographic system Diamond. The TACT® add-on provides means for digital 3D imaging using 2D projection images acquired with the system.

Instrumentarium Corp. Imaging Division

Tommi Jokiniemi
Regulatory Affairs

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Concurence of CDRH, Office of Device Evaulation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002472

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

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